# Exhibit C

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF TEXAS**
**TYLER DIVISION**

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| R.J. REYNOLDS TOBACCO COMPANY; SANTA FE NATURAL TOBACCO COMPANY, INC.; LIGGETT GROUP LLC; NEOCOM, INC.; RANGILA ENTERPRISES INC.; RANGILA LLC; SAHIL ISMAIL, INC.; and IS LIKE YOU INC.<br><br>*Plaintiffs*,<br><br>*v.*<br><br>UNITED STATES FOOD AND DRUG ADMINISTRATION;<br><br>UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES;<br><br>STEPHEN M. HAHN, in his official capacity as Commissioner of the United States Food and Drug Administration;<br><br>ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services;<br><br>*Defendants.* | CIVIL ACTION NO. 6:20-cv-00176 |

**DECLARATION OF FRANCIS G. WALL**

I, Francis G. Wall, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

**Introduction and Background**

1. I am the Executive Vice President, Manufacturing and Finance, and Treasurer of Liggett Group LLC ("Liggett"). I submit this declaration in support of the motion for

preliminary injunction submitted by plaintiffs in the above-captioned action. I have personal knowledge of the facts set forth herein unless stated otherwise.

2. I have been employed by Liggett in various capacities since 1997. Over the past fifteen years, I have held several executive positions, reporting directly to Liggett's President, Chief Executive Officer and/or Chief Operating Officer. I served as Liggett's Chief Financial Officer from 2006 through 2013. My responsibilities include all aspects of Liggett's manufacturing operations, including the following departments: Manufacturing, Engineering and Maintenance, Operations, Finance, Logistics, Science and Quality, Purchasing, and Tobacco Management. I received a Bachelor of Science in Business Administration from the University of Nebraska-Lincoln in 1991 and a Master's of Economics with a focus on International Accounting and Finance from the London School of Economics in 1997. I have been a certified public accountant since 2006.

3. Liggett and its predecessors have been in the tobacco business for over 140 years. Today, Liggett's total market share is approximately 4.0 percent of the United States cigarette market in terms of unit sales.[1] Liggett currently has approximately 500 employees, and its cigarette brands include *Eagle 20's*, *Pyramid*, *Grand Prix*, *Liggett Select*, and *Eve*. As a relatively small manufacturer, Liggett must compete vigorously to maintain its presence in a national market dominated by three much larger manufacturers and also constantly contend with dozens of smaller manufacturers, many of which have a strong regional or local presence. Liggett also manufactures several private label brands that are sold and distributed by certain

[1] Company financial information and operations, such as market share, numbers of cigarette and packaging styles, and costs, as referenced in this declaration reflect the combined data of both Liggett and its affiliate, Vector Tobacco Inc.

retail customers. Liggett manufactures and sells cigarettes only in the United States. The pricing for all of Liggett's cigarette brands is lower than most other brands sold domestically, which positions the company in what is commonly referred to as the "discount segment" of the domestic cigarette market. Liggett exclusively sells cigarettes in the discount rather than premium segment of the domestic cigarette market.

4. This declaration addresses the immediate, substantial, and irreparable harm that Liggett will suffer if forced to comply, during the pendency of this action, with the new cigarette packaging and advertising warning requirements issued by the United States Food and Drug Administration ("FDA") on March 18, 2020. *See* Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 85 Fed. Reg. 15638 (March 18, 2020) (codified at 21 C.F.R. § 1141) (the "Rule"). As discussed below, the Rule will have a severe impact on Liggett's already limited ability to market and sell its cigarettes and imposes compliance costs of at least $20 million. Although the 120-day extension granted on May 8, 2020 delays the Rule's effective date, ultimately the harm imposed on Liggett can only be prevented if the Court enjoins the Rule until it determines whether the Rule is valid.

**The Rule Would Virtually Eliminate Packaging as a Means of Customer Communication**

5. Current law, regulations, and tobacco industry settlement agreements substantially restrict—or in some cases prohibit altogether—cigarette advertising and marketing, leaving the packages themselves as one of the primary lawful means of cigarette marketing. The Rule imposes substantially increased warning requirements by requiring that the top 50 percent of the front and back of each cigarette pack and carton, as well as the top 20 percent of all cigarette advertising, display FDA's mandated graphic warnings.

6. If Liggett were forced to utilize half of its cigarette packs and cartons in the

manner mandated by the Rule, Liggett's efforts to communicate with its customers and sell its products would be severely impaired, and its ability to compete effectively would be greatly undermined.

**The Rule Imposes Severe Economic Costs on Liggett**

7. Even with this Court's order delaying the Rule's effective date, the Rule imposes severe, immediate, and continuing economic costs on Liggett and will cause substantial disruption to its business operations. Liggett estimates that it would incur approximately $20 million or more in costs and expenses to comply with the Rule: $4 to $6 million of costs associated with the printing and design changes of its packaging and advertising and an additional $14 to $16 million due to write-offs for inventory and packaging that would be rendered unusable by the Rule. These estimates do not include additional costs that cannot be easily determined at present, such as the increased costs connected to: the diversion of personnel from regular operations to compliance work related to the Rule; the COVID-19-pandemic; business loss or disruption; and further changes if the Rule or warnings are modified by FDA or the courts. A stay is required because such burdens and costs will begin to accrue immediately as Liggett takes steps to comply with the Rule and will not be recoverable by Liggett if the Rule is ultimately invalidated.

8. Because the Rule imposes substantial changes to the marketing and labeling of its products, to meet the current effective date of October 16, 2021, Liggett must take immediate action to comply with the Rule. If an injunction is not granted, Liggett would incur substantial unrecoverable costs to change all of the packaging (both packs and cartons), and all of the advertising materials, for all of its brands in order to comply with the Rule. Because it would take substantial time, effort and planning to make these changes, Liggett would need to begin to

make these changes and incur these costs immediately. As Liggett is a small company and represents a relatively small percentage of the overall domestic tobacco market, the cost and burden of its compliance with the Rule would impose a disproportionate burden on Liggett, making it difficult to compete; it could also make it commercially impracticable for Liggett to continue to manufacture and sell certain of its brands.

9. Congress afforded manufacturers at least fifteen months to comply with the new warning requirements because it recognized that implementation would be a major undertaking. Family Smoking Prevention and Tobacco Control Act (the "Act"), Pub. Law No. 111-31, 123 Stat. 1776, 1845 (2009); *see also* 85 Fed. Reg. at 15638 (setting effective date fifteen months from publication). The Rule imposes substantial burdens, including requiring Liggett to submit and obtain approval of a plan for how it will provide comply with graphic warnings requirements. *See* Section 4 of the Federal Cigarette Labeling and Advertising Act and 21 C.F.R. § 1141.10(g)(2) (requiring plan for the random and equal display and distribution of the eleven required warnings on cigarette packaging and quarterly rotation of the required warnings in cigarette advertising). FDA has stated that entities required to submit cigarette plans should attempt to do so "as soon as possible," thus imposing imminent deadlines and creating uncertainties as to how Liggett should proceed. FDA has also made clear that it will require six months to review and approve or reject each tobacco company's compliance plan. 85 Fed. Reg. at 15695. Liggett's compliance efforts will be complicated and prolonged if FDA rejects Liggett's initial proposed plan and Liggett must devise and propose an alternative one to FDA.

10. I understand that, in light of the COVID-19 pandemic, the parties have agreed to and the Court has ordered a 120-day extension of the current effective date of the Rule. Liggett requires the requested injunctive relief even with this modest extension, so as to avoid the

irreparable harm described herein. The additional 120 days will not alleviate the enormous burdens placed on Liggett resulting from the Rule, and without the requested injunctive relief Liggett would still be forced to take immediate steps to comply with the Rule as set forth below—steps that will impose substantial and irreparable harm on Liggett if the Rule is ultimately held invalid.

11. Implementing the changes imposed by the Rule would require Liggett to dedicate tremendous time and resources. Liggett would need to work closely with FDA for proper guidance and retain teams of graphic designers, cylinder engravers, printers, and private label partners. To have a realistic chance of meeting the deadlines imposed by the Rule, Liggett would have to begin designing new packaging and developing its new manufacturing processes immediately, and would have to commence the actual printing of packs and cartons with the new packaging by approximately July 2021.

12. Even if Plaintiffs ultimately prevail in this action, Liggett will not be able to recover any of the costs, expenses, or losses it will have incurred in compliance of the Rule.

**Specific Tasks and Costs to Implement Changes**

13. The Rule would require Liggett to redesign every pack and carton of every style of all of its cigarette brands. Liggett manufactures 100 separate cigarette styles, each packaged into packs and cartons. Under the Rule, Liggett would have to replace each current pack and carton design with textual and graphic warnings that consume 50 percent of the front and back of each pack and each carton. Because each of the 200 packages Liggett offers would need to have at least eleven variations to accommodate the new warnings, in all, the Rule would require Liggett to create more than 2,000 distinct packaging designs. In addition to packaging, the Rule's revised warnings would need to be applied to all of Liggett's advertising and marketing

materials. These mandated changes are time-consuming, logistically difficult and extremely expensive. In total, it would cost Liggett millions of dollars to redesign its cigarette packs, cartons, and marketing materials to comply with the Rule.

14. These estimates assume a best-case scenario with respect to the costs Liggett would be forced to incur under the Rule. In its commentary on the Rule, FDA has stated that it would implement any part of the Rule that survives a legal challenge, including, for example, requiring 50 percent text-only warnings if no graphic warning survives. If Liggett is required to implement some combination of warnings that differs from what is presently required by the Rule, Liggett will incur additional, substantial expenses and would consequently require additional time to achieve compliance.

15. Moreover, given the current public health crisis surrounding the COVID-19 pandemic, there is a substantial risk that Liggett, and third parties with which Liggett must coordinate, would be unable to work efficiently to meet the necessary deadlines. Liggett is already encountering situations as a result of the COVID-19 pandemic whereby Liggett's contractual counter-parties are invoking *force majeure* and related legal principles to avoid their obligation to perform under various contracts. Nearly all companies with which Liggett would have to work to comply with the Rule are impacted by, among other things, the supply chain ramifications of the COVID-19 pandemic, even if they not directly impacted themselves. At present, there is no way to predict the additional time and cost of compliance resulting from the ongoing COVID-19 pandemic.

16. In order to comply with the Rule as issued, Liggett would need to address the following specific categories of tasks, each of which would impose substantial burdens on the company: (1) artwork development; (2) pre-print development (*i.e.,* engraving cylinders); (3)

print development; (4) production; and (5) distribution and shipping. Each is discussed below.

17. Liggett would need to work with its outside design agency to develop the new packaging and carton designs for 200 products that would be necessary to comply with the Rule. Liggett would also be required to solicit comments from its private-label customers, who may require additional changes to the packaging.

18. Given the nature of the packaging changes and the number of individual designs, Liggett would need to put in place an extensive internal review and approval process. Numerous departments—including marketing, sales, manufacturing, legal, and purchasing, as well as senior executive management—would need to be involved in the review and approval process. Even under ideal circumstances, this review process would consume more than 1700 employee hours and significant resources. Liggett anticipates that the COVID-19-related prohibitions on in-person meetings would cause substantial, additional delays, costing even more in dollars and employee time, because remote coordination on these tasks would be time consuming and, in some instances, impossible.

19. Liggett anticipates significant costs to change or modify its printing cylinder bases to comply with the Rule. Liggett incurred high costs in anticipation of the change to cigarette graphic warnings in 2011. Liggett reasonably estimates that the total cost for new printing cylinder bases to comply with the current Rule would be similarly high. Each printing cylinder applies a different color of ink to the paper used for the cigarette packs and cartons, so multiple cylinders are needed for each of the new packaging configurations—Liggett will need to have over 900 cylinders engraved in order to comply with the current Rule. Liggett anticipates that it would use WRE/ColorTech and Southern Graphic Systems Inc. for cylinder engraving. These two companies have already informed Liggett that under the best of

circumstances, assuming no work stoppages or other interruptions on account of COVID-19, they have the collective capacity to engrave approximately 100 cylinders per week. Under ideal circumstances, the engraving process would take approximately five or six months, meaning engraving would need to begin by December 2020. This estimate likely materially underestimates the time required to complete the engraving process, especially given the COVID-19 crisis.

20. Only after the packaging artwork is finished and the printing cylinders have been engraved could Liggett begin the process of printing the different variations of new packaging for each of Liggett's roughly 200 products. Based on planning and projections regarding the amount of time needed to make the transition from old to new packaging, I estimate that under ideal circumstances the printing and transition process would be extremely difficult and complex and would consume no less than three to four months. Given the restrictions imposed by COVID-19, it is likely that there would be substantial disruptions and complications at every step of the process. Upon completion of the transition, I anticipate Liggett would incur at least several millions of dollars in additional costs relating to the destruction and write-off of old packaging that cannot be used after the effective date.

21. The Rule's requirement that Liggett display all eleven warnings "randomly" but "equally" across a product line would slow the manufacturing process and drastically increase costs. *First,* Liggett would have to devise and provide FDA with a plan about how it proposes to meet this requirement—and wait months for FDA to approve, reject, or modify the plan. *Second,* executing the plan would require substantial coordination between Liggett and its printers to alter the printing process. Finally, Liggett would incur substantial costs to meet FDA's requirement that the warnings not only be printed randomly and equally but also be

distributed in such a fashion. Even if FDA permits a reasonable deviation in the distribution of the warnings across packaging (*e.g.*, 10 percent), the cost to Liggett would be substantial.

22. Part of the complexity of the overall packaging transition required by the Act and the Rule lies in the fact that not all product styles sell at the same rate—there are faster and slower selling brands and styles within brands. Packaging, however, must be ordered in certain minimum quantities to avoid the excessive costs of special quantity orders. Obviously, a pallet of packaging lasts longer for a slower-selling style than it does for faster selling styles, so it is not possible to apply a "one-size-fits-all" transition schedule to all product styles. The effort to schedule a cost-efficient packaging transition is made more complicated because the available inventory of packs and cartons for a particular style would almost never be exhausted at the same time. The more time that is available for the transition, the better the transition can be managed to minimize the extraordinary costs and disruptions to efficient operations—and it would be vastly preferable to avoid incurring the costs of transition altogether, if the Rule is modified or invalidated.

23. The limited number of companies that engrave cylinders and print packaging also complicates scheduling and raises costs in the transition from old to new packaging. Because the total industry would have to overhaul its entire packaging process, many different cigarette manufacturers would be competing for finite engraving and printing capacity. Liggett, for example, uses two printers—Dominion Packaging and Amcor Specialty Cartons. Dominion and Amcor also print for the three largest cigarette manufacturers in the United States—Philip Morris, R.J. Reynolds, and ITG Brands—which have a combined share of more than 80 percent of the domestic cigarette market. In addition, Dominion has other customers (such as McDonald's) that require press time for their packaging needs. This not only complicates

scheduling but also means that some cigarette manufacturers would need to begin incurring costs earlier than others to meet the same deadline.

24. The Rule's revised warnings must be implemented not only on packaging, but also on advertising. The Rule requires the top 20 percent of all advertising to contain the new graphic warnings, so new advertising will need to be created and distributed. Most immediately, this impacts the company website and retail point-of-sale advertising. Liggett will need to implement substantial updates to its website and redesign, print, and replace all point-of-sale communications at each of at least 35,000 retailers. New advertising would need to be designed, printed, and installed, removing old point-of-sale advertising in the process.

25. The removal and replacement of all marketing materials at retail stores is estimated to take Liggett's sales representatives at least four months. Liggett anticipates point-of-sale materials would cost upwards of one million dollars to produce, deliver, and store. Implementation of these changes would be particularly complex because of Liggett's relatively small number of retail sales representatives.

26. Distributing Liggett's finished goods would also take time and careful planning and would require Liggett to incur substantial costs to comply with the Rule. Once the cigarettes are manufactured at Liggett's factory in North Carolina, they are shipped to fifteen different public warehouses around the country. Because the Rule requires that all cigarettes introduced into commerce by the effective date must bear the new warnings, Liggett would need to have all fifteen warehouses fully stocked with product in new packaging by that date (with all eleven warnings randomly and equally distributed in each), and would also need to have already removed from the fifteen warehouses all old packaging inventory. To exhaust the inventories of old packaging without having to bear the excessive cost of discarding huge quantities of it, and

to have enough time to manufacture sufficient quantities of the new packaging product in time to fully stock all of its warehouses by the current effective date deadline, Liggett would necessarily need to be manufacturing product in the new packaging at least several months before the effective date of the Rule. And to ensure a smooth transition and avoid having to place expensive special orders for small quantities of packaging or incur large write-off costs from discarding old packaging materials or finished goods in old packaging, Liggett would need to begin shipping product in new packaging a month or more before the Rule's effective date.

27. For some of Liggett's product lines, the compliance costs associated with the Rule may make them economically unviable. Thus, certain Liggett products that have been on the market for decades might need to be discontinued because Liggett would not be able to comply with Rule without incurring substantial losses on those products. Pulling a product from the market is a last resort, and it would be effectively impossible to reverse such a step if the Rule is ultimately determined to be invalid.

28. If the requested stay or injunction is not granted, Liggett would be forced to comply with a challenging schedule to satisfy the deadlines imposed by the Rule. Thus, in addition to the losses resulting from making the many expensive changes to the packaging and marketing materials for all of its cigarette brands, Liggett would be left with an inventory of approximately $16 million (depending on the number of days of inventory) worth of cigarettes carrying the invalidated warnings. These cigarettes could not be sold because cigarette packages that fail to carry a valid warning are "misbranded" under the Act and cannot be lawfully sold. 21 C.F.R. § 1141.12. These "misbranded" cigarettes cannot be re-packaged, and the value of the unusable packaging and reclaimed tobacco, if any, is minimal at best.

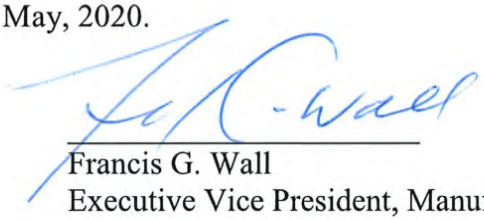
29. Many considerations and variables—some of which are beyond Liggett's

control—would need to be taken into account and coordinated to achieve a smooth and cost-effective transition of all packaging across a company's entire product line. As Congress recognized, it certainly is not simply a matter of "flipping a switch" and quickly or easily changing from old packaging to new. The process is complex, and requires extensive planning and long lead times if it is to be accomplished on any reasonable basis without unnecessary and burdensome extra costs, and without debilitating disruptions in the manufacturing and distribution processes.

**Conclusion**

30. Based on the company's estimates, Liggett would incur costs of approximately $20 million in order to comply with the Rule. This number does not include additional burdens and expenses imposed by the Rule that cannot presently be calculated, such as the resulting substantial disruption to Liggett's business operations. Thus, if the requested preliminary injunction is not granted, Liggett will be forced to incur substantial burdens and costs that cannot be recovered by Liggett if the Rule is ultimately held to be invalid. Absent the requested injunctive relief, Liggett will have no choice but to continue its efforts to comply with and implement the Rule in accordance with an extremely challenging schedule. Based on the foregoing, the burdens and costs for Liggett to comply with and implement the Rule would be extraordinary and unrecoverable and would cause irreparable harm to the company.

Respectfully submitted, this 14th day of May, 2020.



Francis G. Wall
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